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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,329	07/09/2001	Joachim Messing	13259-00011	4832

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,329

Applicant(s)

MESSING ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,13,14,16,17 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,13,14,16,17,22-27,29 and 30 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The amendment to the first page of the specification, inserting a sentence to claim priority to earlier applications, has been entered.
3. The objection to the specification is withdrawn.
4. The rejection of claims 1 and 5-7 under 35 U.S.C. 101 is withdrawn, in light of the claim cancellations.
5. The rejection of claims 1-18 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim cancellations and amendments.
6. The rejection of claim 16 under 35 U.S.C. 112, 1st paragraph, is withdrawn in light of Applicants' arguments in the paper submitted July 15, 2003.
7. The rejection of claims 1, 2, 5, 8-10, and 12 under 35 U.S.C. 102(e) is withdrawn, in light of their cancellation.

Claim Objections

8. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

9. Claims 11, 13, 14, 17 remain and new claims 22-27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed January 16, 2003 under item 7. Applicants traverse in the paper submitted July 15, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the amended and new claims are directed to subject matter that is adequately described by the specification (response, page 12, 1st full paragraph). However, the amended and new claims are broader in scope than the originally examined claims, in that the chimeric gene can now comprise the coding region of any 10 kDa zein, from any source. As discussed previously, the specification only describes the coding region of the maize 10 kDa delta zein.

10. Claims 11, 13, 14, and 17 remain and new claims 22-27, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed January 16, 2003 under item 8. Applicants traverse in the paper submitted July 15, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the amended and new claims are directed to subject matter that is adequately enabled by the specification (response, page 12, 1st full paragraph). However, as discussed above, the chimeric gene of the claims can now encompass any 10 kDa zein coding region. However, the specification only enables the claimed invention when the coding region is from the maize 10 kDa delta zein gene. The specification also does not teach that methionine content of corn seeds can be increased by transgenically expressing other types of 10 kDa zeins.

11. Claims 11, 13, 14, 16, 17, and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a method of making high methionine corn seeds that produce saturation levels of any 10 kDa zein regardless of the *dzt1* allelic composition of the seed, comprising transforming corn plant cells with a vector comprising a chimeric gene

encoding any 10 kDa zein, operably linked to any promoter at its 5' end and to a heterologous 3' UTR at its 3' end, regenerating a fertile transformed plant, and producing seeds from the plant, wherein the seeds express the chimeric gene and produce saturation levels of the 10 kDa zein; a fertile transgenic corn plant produced by said method.

The specification teaches the construction of a plant transformation vector, pJM2710, in which the coding sequence of the maize 10 kDa delta zein is operably linked to the 27 kDa zein gene promoter and the CaMV 35S 3' polyA sequence. Transgenic maize plants comprising the vector were produced. The transgenic plants exhibited a higher level of expression of the 10 kDa delta zein as compared to non-transgenic Mo17. Progeny of crosses between the transgenic plant and Mo17 expressed high levels of the 10 kDa delta zein regardless of the direction of the cross (pages 24-29, Examples 1-5).

However, the specification does not describe a method of making high methionine seeds that produce saturation levels of 10 kDa zein. There is no written description support in the specification for producing "saturation levels" of any 10 kDa zein. This is a **NEW MATTER** rejection.

Claim Rejections - 35 USC § 103

12. Claim 11 remains and claims 17, 22-25, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagga et al. (U.S. Patent No. 5,990,384) in combination with Hirt et al. (Curr. Genet., 1990, Vol. 17, pages 473-479) and Gordon-Kamm et al. (Plant Cell, 1990, Vol. 2, pages 603-618), for the reasons of record stated in the Office action mailed January 16, 2003

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under item 11. Applicants traverse in the paper submitted July 15, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that since it was not known prior to the instant invention that the *dzr1* gene product negatively regulated the 10 kDa zein, *via* its 3' UTR, there could be not motivation or suggestion to combine the cited prior art references to produce the presently claimed invention, drawn to a method to solve the problem of negative regulation of the 10 kDa zein, which also comprises expressing the 10 kDa zein regardless of the *dzr1* allelic composition of the seeds (response, page 15, 1st full paragraph).

However, first, it is noted that if the host corn plant does not have a *dzr1* allele, then there is no problem of negative regulation of the 10 kDa zein to be solved. Further, the motivation to do what Applicants have done does not have to be the same as the Applicants' to reach a conclusion of obviousness. "It is sufficient if the prior art clearly suggests doing what [applicants] have done, although the underlying explanation of exactly why this should be done, other than to obtain the expected superior beneficial results, is not taught or suggested in the cited references." *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967). The prior art teaches the production of transgenic corn plants in which the 10 kDa delta zein is overexpressed, including in seeds, wherein the transgenic material comprises the coding region of a maize 10 kDa delta zein operably linked to a promoter and a heterologous 3' UTR, as does the claimed invention. Applicants are of the opinion that the claimed invention is unobvious because it wasn't known that *dzr1* negatively regulates the 10 kDa zein through its 3' UTR. However, the reason for replacing the 3' UTR in the prior art does not have to be the same as that of the Applicants. The instant claims indicate that it does not matter what the *dzr1* allele

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composition of the corn plant is. Therefore, this recitation does not limit any prior art host corn plant. The prior art also does not limit the *dzt1* allelic composition of the host corn plant to be transformed. It also would have been obvious to cross the transgenic corn plants with other corn plants, for the purpose of producing further generations of plants that comprise the chimeric gene and whose seeds produce an increased amount of methionine.

13. Claims 11, 13, 14, 17 remain and claims 22-27, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiriwara et al. (Mol. Gen. Genet., 1988, Vol. 211, pages 477-484) in combination with Russell et al. (Trans. Res., Vol. 6, 1997, pages 157-168), and Hirt et al. (Curr. Genet., Vol. 17, 1990, pages 473-479), for the reasons of record stated in the Office action mailed January 16, 2003 under item 12. Applicants traverse in the paper submitted July 15, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present the same argument as for the rejection above. Applicants' argument is not found persuasive, for the reasons discussed above.

Summary

14. Claims 11, 13, 14, 16, and 17 remain and claims 22-27, 29, and 30 are rejected. Claim 28 is objected.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 28, 2003



Ashwin D. Mehta, Ph.D.
Primary Examiner
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